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14. ABSTRACT

ElectroSonics Medical has developed a small handheld system for detecting Pneumothoraces in soldiers in far forward battlefield conditions. Based on Micropower Impulse Radar technology, the system uses is light weight, consumes low power, and is easy to use and interpret. The current design integrates with the MC70 hand held computer which is part of the MC4 computing platforms. It can run on any computing platform that complies with USB 2.0 and is running a Microsoft operating system of XP or later. The system has passed all IEC 60601 test requirements and is being CE Marked for initial use in European clinical trials. One study in Switzerland has been completed and a publication is pending demonstrating the performance of the system in a trauma setting.

15. SUBJECT TERMS
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Contents

Introduction:
This document represents the final report for work performed by ElectroSonics Medical under a grant through the United States Army Medical Research and Materiel Command (USAMRMC). The technical objectives that form the scope of work support the development and clinical testing of a non-invasive pneumothorax detector. Goal and objectives are reflected in the formal approved grant. Uncertainty in the current and near-future computational devices carried by the medic made it prudent to develop a PTX detector that will operate on a surrogate computational device. As there are many possible insertion points of the PTX detector technology, it is more important to maintain a flexible interface that can be easily adapted to the different medical devices along the continuum of care.

Note: Since the submission of the initial proposal, ElectroSonics Medical, Inc has created a wholly-owned business unit called PneumoSonics to carry out the development of their pneumothorax detector. In this document ElectroSonics and PneumoSonics will be used interchangeably.

Military Relevance:
Pneumothorax (PTX) continues to be a leading cause of preventable death on today's battlefield. It has proven to be very difficult to quantify the causes of death on the battlefield. Studies to date have retrospective in nature. This consists of reviewing data in repositories such as the Wound Data and Munitions Effectiveness Team database. Work by Bellamy [1] and Champion [2] indicate that tension pneumothorax is the cause of death in 10% and 5% of soldiers killed in action in Vietnam and Operation Desert Storm respectively.

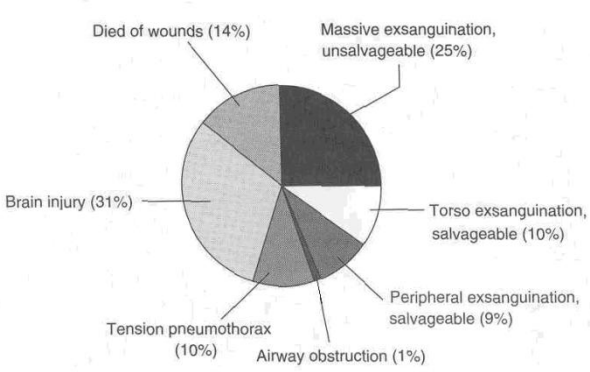


FIGURE 1-1 Distribution of fatal battlefield injuries in Vietnam. SOURCE: Adapted from Bellamy (1984, 1987a,b, 1995).

In Congressional testimony, Air Force Surgeon General George P. Taylor stated that "pneumothorax is a combat killer." General Taylor went on to explain that medics were issued angiocath needles to perform life-saving needle thoracentesis in the case of tension pneumothorax.[1]Tension pneumothorax is a life-threatening condition that requires immediate treatment. This condition can grow out of a simple non-threatening pneumothorax spontaneously. Current practice today in the Special Forces includes the placement of a chest tube by the medic (a difficult and dangerous procedure for a medic in the field) in all cases of penetrating thoracic injury before evacuation.

Pneumothoraces are very difficult to diagnose even in the hospital setting. A civilian postmortem study found 77 cases of pneumothoraces in a population of 3,500 patients. Of these 77, almost half (37 patients) were undiagnosed [3]. Iatrogenic pneumothoraces (due to medical care or medical procedures) remain a problem. During 2000-2002, 33,571 cases (1.011 per 1,000 hospitalized at risk patients) of iatrogenic pneumothorax occurred in the US, resulting in 6,234 deaths (18.57%) [4]. The rate for combat support hospitals and forward surgical teams is not known, but is likely to be greater.

Work by Army medical researchers has determined that a simple needle decompression technique can be performed by the medic in cases of life-threatening pneumothorax. However in the field and in the hospital, a simple device to detect pneumothorax and also detect the reinflation of the lung after needle thoracentesis or chest tube placement would be of great benefit to the Army and save lives of soldiers.

Since 1995, MRMC has funded research into the development of a small low-powered device that medics could use to detect PTX. The work laid out in this document represents part of the effort in this area.

Body:
Working with technology from Lawrence Livermore National Labs (LLNL), ElectroSonics Medical, Inc. (EMI) has developed pneumothorax detection devices based on patented Micropower Impulse Radar (MIR) technology. This device emits very low power radio frequency impulses of a very high frequency and broad spectrum (1-4 GHz). The resultant echoes are collected by extremely high-speed circuitry and analyzed by a proprietary software algorithm. EMI has miniaturized the MIR electronics and developed the software to allow the detector to operate on a multitude of host platforms. All power is drawn from the host, therefore no additional power sources are necessary. The PneumoScan consists of a handheld sensor which includes the MIR circuitry and antenna. This sensor will transmit the received signals to the operating computer platform for processing.

Objectives:
During the first year of development we completed the development of the hardware designed to operate in conjunction with any number of computational devices in use at the time by military medics and clinicians throughout the continuum of military clinical care. Each specific research task as defined in the proposal will be addressed in this report. This will include design of a miniaturized MIR board to include the complex integration of analog and digital electronics on a single board, software engineering necessary to port the code to a portable computing device and the development of a graphical user interface.

In year two we continued to evaluate the device in a clinical setting, developed the protocols for a pivotal study to support an FDA PMA submission, and promoted the system through peer reviewed publications. A phase 2-type human use trial to demonstrate the safety and efficacy of the system is required as part of the regulatory requirements to allow distribution of the product. This study has not been initiated due to regulatory hurdles, financial constraints, and changes in management.

In the final year of development we finalized the manufacturing documentation and continued assessment of the system in European post release clinical studies. An additional study was done at the Massachusetts General Hospital to assess the PneumoScans capabilities in a trauma setting.

Objective 1: Hardware Integration

In year one (1) of the project we completed the development of the PneumoScan system as shown below. scan locations, allows one-handed operation, and is small enough to fit into an existing side pouch on the medic pack.

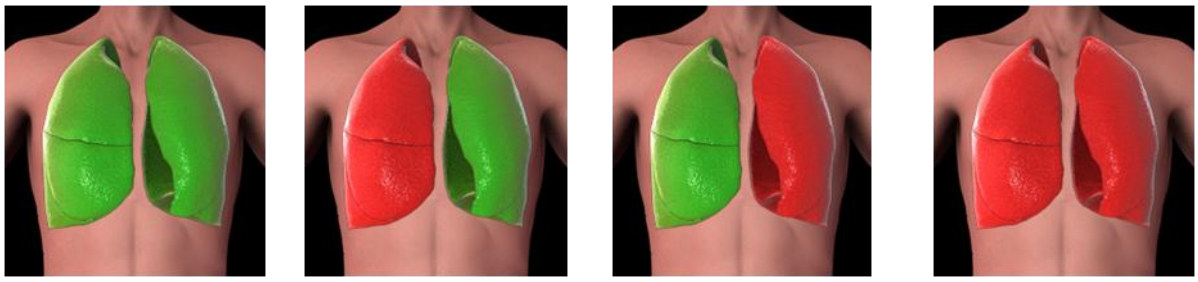
FIGURE 1: PneumoScan and MC75 Operating Platform

In year two we restructured the software to allow the operating software to operate on and Windows operating system and for multiple language use. This gives the device more flexibility in how it is deployed.

Objective 2: Software Development

In year two of the grant we upgraded the software to run on different platforms. The software and firmware was written to Allow for multiple language use and for operation on any computer platform running a windows operating system.

No changes were made to the core algorithm. The system is a simple user interface which displays easily interpreted results as shown below.



No Pneumothorax Detected | **Pneumothorax on the right side** | **Pneumothorax on the left side** | **Pneumothorax on both sides**

FIGURE 4: Possible outcomes of a successful PneumoScan read.

This simple user interface provide easily interpreted results in less than a minute, allowing the medic to quickly assess the patient's condition and determine the best course of treatment.

System Verification Testing:
The final testing required for military use is the formal airworthiness testing which will be completed in conjunction with the formal clinical studies so that a comprehensive system evaluation can be made and all regulatory requirements satisfied. We did not complete the air worthiness testing due to cost issues and timing issues. The air worthiness testing was to coincide with the formal FDA clinical trials which could not be initiated. Several issues with both the immense cost of the PMA trials and the logistics of obtaining informed consent prevent us from completing these tasks.

Manufacturing Transfer:
The design was frozen and we continue to manufacture units for use in clinical trials in both the U.S. and Europe. We have an approved manufacturer who is ISO 13485 certified with extensive medical device manufacturing experience.

Objective 3: Human use study
The third and final objective of this program was to complete clinical evaluations in a trauma setting. We have finalized the protocols and have IRB approval at three sites. Since the study is a PMA it will take 18 months to complete the trials. It is estimated that an additional 6 to 9 months will be required to achieve regulatory approval. The cost of this study will be from $750 K to $ 1 Million. This far exceeds the anticipated costs to achieve regulatory clearance. Due to the excessive costs of this clinical study, it was determined that we are unable to proceed at this point.

We continue to work with Massachusetts General Hospital to evaluate the system in a trauma setting. Additional studies have been initiated in Switzerland and Germany. These studies will be used to promote the product in Europe and to support the clinical evaluations in the U.S. Each of these researchers has successfully utilized the PneumoScan in their clinical practices. We continue to provide them with technical support.

Key Research Accomplishments

1. Develop the Pivotal clinical study protocol and gained IRB approval at three sites.
2. Redesigned the software to operate on the windows operating platform.
3. Added multi-language capabilities to the system.
4. Completed a phase I study of the system in Switzerland and at Massachusetts general Hospital.
5. Achieved three publications for in peer reviewed journals.

Reportable outcomes

Based on this research at this time there are no reportable outcomes. PneumoSonics intends to apply for further funding to support expanding the applications of MIR technology into other diagnostic areas. These include hematoma detection, pneumothorax volume detection, and vital signs monitoring. These technologies can be developed using the existing platform with expanded software and new algorithms.

Conclusions

PneumoSonics Inc. (PSI) has developed and is clinically testing a portable medical device, PneumoScan™, to rapidly detect the presence of a pneumothorax. PneumoScan is non-invasive and provides timely, objective results on the presence and location of a pneumothorax. In feasibility clinical human testing PneumoScan accurately detected the presence of pneumothorax with 93% sensitivity and 85% specificity. The device is portable, easy to use, requires minimum training to operate, and provides objective results in less than one minute that do not require any interpretation.

The device is currently available for sale in Europe under the Medical Device Directorate. Final airworthiness system evaluation must be completed as well as the pivotal clinical evaluations required by the regulatory agencies prior to release for use by U.S. military personnel. Methods to fund these studies are being evaluated.

References

1. Presentation by Lieutenant General (Dr.) George Peach Taylor Jr., Air Force Surgeon General to the Military Personnel Subcommittee of the House Armed Services Committee, October 19, 2005.
2. Belamy RF, The Causes of Death in Conventional Warfare. Military Medicine, Feb 1984
3. Champion HR, A Profile of Combat Injury. J of Trauma, May 2003
4. Ludwig J, Pneumothorax in a large autopsy population. A study of 77 cases. Am J Clin Pathol Jul 1978
5. Patient Safety in American Hospitals, Health Grades 2004
6. Holcomb, J. B. et al., Efficacy of Needle Thoracostomy for Relieving Tension Pneumothorax in an Anesthetized Porcine Model. 1999. Unpublished Work.

Appendices

N/A